IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Otterbein et al.
Serial No. : 10/600,182
Filed : June 20, 2003
Title : PHARMACEUTICAL USE OF NITRIC OXIDE, HEME OXYGENASE-1 AND PRODUCTS OF HEME DEGRADATION

Art Unit : 1618
Examiner : Dameron Levest Jones

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO RESTRICTION REQUIREMENT

Responsive to the action mailed July 25, 2005, applicants elect the invention of Group 33 (claims 16 to 20), drawn to methods of transplanting an organ, tissue, or cells, wherein the pharmaceutical composition comprises carbon monoxide. This election is made with traverse for the reasons discussed below.

The instant claims are directed to methods comprising administering a pharmaceutical composition comprising nitric oxide and a second treatment selected from inducing or expressing heme oxygenase 1 (HO-1), inducing or expressing ferritin, or administering a pharmaceutical composition comprising HO-1, carbon monoxide, bilirubin, biliverdin, ferritin, iron, desferoxamine, salicylaldehyde isonicotinoyl hydrazone, iron dextran, or apoferritin. As an initial matter, applicants respectfully point out that the Restriction Requirement did not include any groups related to second treatments involving inducing or expressing HO-1 or ferritin. Applicants are proceeding based on the assumption that these embodiments were inadvertently left out of the Restriction Requirement due to a clerical error, and would have been included in additional restriction groups had the error not been made.

Applicants respectfully submit that Groups 32 to 41 (all of which include claims 16 to 20) should be recombined into a single group because they are closely related. All of these claims relate to transplantation procedures involving administering a pharmaceutical composition comprising nitric oxide to a patient (e.g., a donor and/or recipient in a

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transplantation procedure), or to an organ or cell removed from a patient, in conjunction with a second treatment (described above). Because the embodiments are closely related, applicants submit that the same body of literature will be searched for all of these claims prior to examination. Indeed, the Restriction Requirement itself suggests that this is the case, stating that all of them belong to the same search class (class 424) and subclass (9.1). Furthermore, one would expect similar or at least overlapping search terms to be employed for all of these searches. For example, a search for methods of transplantation that include administering a pharmaceutical composition comprising nitric oxide would likely find literature describing nitric oxide in combination with a second treatment (assuming any such literature exists). Thus, there would seem to be no undue burden on the Examiner to search the subject matter of all of these Groups at the same time.

Further, applicants submit that Groups 1 to 31 (all of which include claims 1 to 15) should be recombined into a single group. These claims relate to methods of reducing inflammation in a patient. Independent claim 1 is a generic claim, and it does not recite disorders associated with the inflammation. The Office has required restriction of claim 1 based on dependent claim 13, which recites a non-exhaustive and non-limiting list of conditions which are associated with inflammation. Applicants respectfully submit that restriction of claim 1 into thirty-three different claims based on the disorders recited in dependent claim 13 is improper, since doing so would prevent applicants from pursuing the full scope of the generic claim 1. Although claim 15 does recite a Markush group of species of disorders associated with inflammation, applicants submit that the species are closely related, and that there would seem to be no undue burden on the Examiner to search the subject matter of all these species at the same time.

Applicants also submit that Groups 42 to 51 (all of which include claim 21) should be recombined into a single group because they are closely related. All of these Groups relate to methods of performing angioplasty on a patient involving administering a pharmaceutical composition comprising nitric oxide to the patient in conjunction with a second treatment. Because the embodiments are closely related, applicants submit that the same body of literature will be searched for all of these claims prior to examination. The Restriction Requirement itself suggests that this is the case, stating that all of them belong to the same search class (class 424)

and subclass (9.1). One would expect similar or at least overlapping search terms to be employed for all of these searches. Thus, there would seem to be no undue burden on the Examiner to search the subject matter of all of these Groups at the same time.

Finally, applicants submit that Groups 52 to 61 (all of which include claims 22 and 23) be combined into a single group because they, too, are closely related. All of these Groups relate to methods of treating naturally arising cancer by administering to a patient a pharmaceutical composition comprising nitric oxide in conjunction with a second treatment. Because the embodiments are closely related, applicants submit that the same body of literature will be searched for all of these claims prior to examination. Thus, there would seem to be no undue burden on the Examiner to search the subject matter of all of these Groups at the same time.

To summarize, based on the above, applicants request that the Office reconsider the present Restriction and recombine Groups 1 to 31 into a single, first group, Groups 32 to 41 into a single, second group, Groups 42 to 51 into a single, third group, and Groups 52 to 61 into a single, fourth group. Were the Office inclined to do so, applicants would then elect the invention of the group formed from the combination of Groups 32 to 41.

Regarding a species election for Groups 32 to 41, the Restriction Requirement states:

> Applicant is respectfully requested to elect a single disclose species from within the elected group for search purposes. If appropriate for the elected group, Applicant is respectfully requested to identify the pharmaceutical composition (e.g., if one of Groups 1-31 is elected); the type of cancer (e.g., if one of Groups 24 or 52-61 is elected); and the organ being transplanted (e.g., if one of Groups 32-41 is elected).

Based on the language of the Restriction Requirement, applicants are uncertain as to whether a species election is required for Groups 32 to 41 and request clarification. Applicants would prefer not to elect a species if they are not required to do so. However, if so required, applicants would elect a species of kidney as the organ to be transplanted. Applicants further note that no claims reciting species of organ being transplanted were presented in the application. Since only generic claims to transplantation were presented, applicants submit that a requirement of species election for Groups 32 to 41 would not be proper.

Enclosed is a check for $2,160 for the Petition for Extension of Time fee. Please apply any other charges, or any credits, to Deposit Account No. 06-1050, referencing Attorney Docket No. 13681-012001.

Respectfully submitted,

Date: 1/24/06

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